

*****MISSOURI BOARD OF PHARMACY
COVID-19 RULE UPDATES***
(3-20-20)**

On March 13, 2020, Governor Parsons issued [Executive Order 2020-02](#) which declared a State of Emergency after confirmed and/or presumptive positive cases of COVID-19 in Missouri. Governor Parsons subsequently issued Executive Order 2020-04 which granted Boards within the Division of Professional Registration authority to temporarily waive or suspend the operation of statutory rule or administrative requirements to best serve public health and safety.

Pursuant to [Executive Order 2020-04](#), the following provisions of Missouri law are being waived during the State of Emergency subject to the following restrictions/requirements:

STATUTE/RULE WAIVED	Description
§ 338.200.1(2)	<u>Emergency Dispensing:</u> Pharmacies may dispense an emergency supply of medication to a patient if the pharmacy that originally filled the prescription is closed or unable to fill the prescription due to the State of Emergency. Pharmacists must make a good faith effort to verify the medication to be dispensed and the authorized prescriber and dosage form (e.g., as listed on the patient’s prescription vial). <i>**This waiver applies to non-controlled substances only; § 338.200 does <u>not</u> apply to controlled substances.**</i>
§ 338.200.2(1)	<u>Emergency Dispensing:</u> Pharmacies/pharmacists may dispense up to a thirty (30) day supply of emergency medication pursuant to § 338.220 during the State of Emergency. For unit of use medications that exceed a 30 day supply, the smallest unit of use available in inventory may be dispensed for emergency purposes.
20 CSR 2220-2.010(1)(A)	<u>Dispensing Verified Medication:</u> Pharmacy technicians or an intern pharmacist may dispense medication to the patient when a pharmacist is not physically present in the pharmacy due to the State of Emergency if: <ol style="list-style-type: none"> 1) The medication has been previously verified by a pharmacist and approved for dispensing, 2) Dispensing is necessary for patient safety or to provide disaster or emergency relief, and 3) Dispensing without the pharmacist present is approved by a pharmacist or pharmacy in advance.
20 CSR 2220-2.010(1)(B)	<u>Remote Product Verification:</u> To prevent illness and staffing shortages, a pharmacist may use technology to remotely verify the final product as required by 20 CSR 2220-2.010 if needed to provide disaster or emergency relief if: <ol style="list-style-type: none"> 1. Physical verification by a pharmacist cannot be promptly performed by a pharmacist;

	<p>2. Prompt dispensing is in the best interest of the patient’s health and safety;</p> <p>3. The technology used is sufficient to allow the pharmacist to properly and accurately inspect and verify the accuracy of the contents of the prescription or medication order and the affixed label, and</p> <p>4. If the pharmacy technician or intern pharmacist is supervised in compliance with proposed rule 20 CSR 2220-2.710 published in the Missouri Register on March 16, 2020. In lieu of the required initial competency assessment referenced in 20 CSR 2220-2.710(2)(C), pharmacy technicians and intern pharmacists must be deemed competent to perform the duties assigned by the pharmacist-in-charge.</p>
20 CSR 2220-2.200(10)(B)	<p><u>Sterile Compounding</u>: Pharmacies engaged in sterile compounding may accept Aseptic Technique Skill Assessment results (including media-fill testing) from another pharmacy for the same staff member, if needed to prevent interruptions in patient care or to ensure availability of pharmacy services during the State of Emergency. However, pharmacy technicians should be trained on pharmacy operational procedures to ensure proper aseptic technique.</p>
20 CSR 2220-2.650	<p><u>Class-J Shared Services</u>: During the State of Emergency, a Missouri licensed pharmacy may provide shared pharmacy services identified in 20 CSR 2220-2.650 for another Missouri licensed pharmacy without a Class-J Shared Services permit, if the shared services are necessary to prevent interruptions in patient care as a result of pharmacy closures, limited staffing or interruptions in pharmacy operations due to COVID-19. Both pharmacies must comply with 20 CSR 2220-2.650 with the following exceptions:</p> <ol style="list-style-type: none"> 1. A common database or shared real-time access to each pharmacy’s electronic medication or prescription system is not required during the State of Emergency, if such database or real-time access cannot be promptly arranged in sufficient time to meet patient care needs during the State of Emergency. Pharmacists should use their professional judgment to ensure appropriate patient care and medication dispensing. 2. Pharmacies may participate in a shared services arrangement authorized by this directive without a written contract outlining authorized shared services required by 20 CSR 2220-2.650(1)(A)1. or the policy and procedure manual required by 20 CSR 2220-2.650(1)(C)1., if such contract or policy/procedure manual cannot be timely completed to meet patient needs during the emergency. However, authorized shared services should be documented in advance in writing, including, designation of the pharmacy responsible for offering patient counseling as required by 20 CSR 2220-2.190 and federal law. 3. Pharmacies operating under the above allowances must comply with all provisions 20 CSR 2220-2.650 once the State of Emergency ends or upon Board termination of this authorization. A Class-J Shared Services permit and full compliance with the rule will be required at the end of the State of Emergency/Board authorization. <p><i>*** The above allowances only apply to pharmacies providing shared services to a Missouri licensed pharmacy to prevent interruptions in patient care as a result of pharmacy closures, limited staffing or interruptions in pharmacy operations due to COVID-19.</i></p>

	<i>All other pharmacies/shared services arrangements must comply with 20 CSR 2220-2.650.</i>
20 CSR 2220-6.055(6)	<u>Non-Dispensing Activities:</u> Pharmacists may use pharmacy technicians and intern pharmacists to assist a pharmacist with non-dispensing functions from an off-site non-pharmacy location during the State of Emergency. Pharmacists should use their professional judgment to ensure technicians/intern pharmacists are appropriately supervised.
20 CSR 2220-2.700(1) & 20 CSR 2220-6.055(6)	<u>Remote Data Entry:</u> Pharmacy technicians and intern pharmacists may perform remote data entry activities from home or outside of a licensed pharmacy, if the pharmacy complies with the provisions of proposed rule 20 CSR 2220-2.725 published in the Missouri Register on March 16, 2020. In lieu of the required initial competency assessment referenced in proposed 20 CSR 2220-2.725(3)(C), pharmacy technicians and intern pharmacists may perform authorized remote data entry functions if approved and deemed competent to perform the duties assigned by the pharmacist-in-charge.

The above waivers are intended to address the State of Emergency and should not be used for pharmacy convenience or to decrease costs. The Board will continue to monitor waiver requests and may issue further guidance as events develop. Pharmacists are vital members of the healthcare team and can play a critical role in providing patient care during the State of Emergency. Pharmacists should exercise their professional judgment to ensure safe and appropriate patient care. Questions can be addressed to the Board office at (573) 751-0091 or at MissouriBOP@pr.mo.gov. Due to the volume of phone calls at this time, e-mails are preferred.

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SALUS POPULI SUPREMA LEX ESTO

“The welfare of the people shall be the supreme law.”



JOHN R. ASHCROFT
SECRETARY OF STATE

MISSOURI
REGISTER

Title 20—DEPARTMENT OF COMMERCE AND INSURANCE
Division 2095—Committee for Professional Counselors
Chapter 3—Professional Responsibility

PROPOSED AMENDMENT

20 CSR 2095-3.015 Client Welfare. The committee is amending sections (1) and (7).

PURPOSE: This rule is being amended to address the need for a client or patient to understand the parameters of distance based counseling.

(1) Before beginning a therapeutic relationship, a counselor shall explain and document the following elements of informed consent:

(G) Limits to confidentiality regarding individual, couple, family, and group therapy; *[and]*

(H) If utilized, taping or recording of sessions, and how the tapes will be used and stored.; *and*

(I) When using technology in the course of providing professional counseling, how such technology is in compliance with federal and state legal and ethical requirements.

(7) A counselor providing therapeutic services to a client shall maintain records that include the following:

(A) Informed consent as defined in *[subsections (1)(A)–(H)]* section (1);

AUTHORITY: section[s] 337.520, *RSMo Supp. 2019*, and section 337.525, *RSMo [2000] 2016*. This rule originally filed as 4 CSR 95-3.015. Original rule filed Dec. 1, 2004, effective June 30, 2005. Moved to 20 CSR 2095-3.015, effective Aug. 28, 2006. Amended: Filed Feb. 14, 2020.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Committee for Professional Counselors, PO Box 1335, 3605 Missouri Boulevard, Jefferson City, MO 65102-1335, by facsimile at (573) 751-0018, or via email at prof counselor@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this rule in the *Missouri Register*. No public hearing is scheduled.

Title 20—DEPARTMENT OF COMMERCE AND INSURANCE
Division 2220—State Board of Pharmacy
Chapter 2—General Rules

PROPOSED RULE

20 CSR 2220-2.710 Pharmacy Technician and Intern Pharmacist Supervision

PURPOSE: This rule defines the required supervision for pharmacy technicians and intern pharmacists.

(1) Pharmacy technicians and intern pharmacists may assist a pharmacist in the practice of pharmacy as authorized by Chapter 338, RSMo, and the rules of the board, provided delegated tasks are per-

formed under the direct supervision of a pharmacist. Direct supervision means supervision by a Missouri licensed pharmacist who is readily and immediately available at all times the delegated tasks are being performed and who provides personal assistance, direction, and approval throughout the time the delegated tasks are being performed. “Readily and immediately available” means the pharmacist and pharmacy technician(s) or intern pharmacists are on the same physical premises, or if not, technology is used to communicate with and observe the pharmacy technician and intern pharmacist, as authorized in section (2).

(2) Use of Technology. Except as otherwise provided by law or regulation, technology may be used to directly supervise a pharmacy technician and intern pharmacist, provided:

(A) Sufficient technology is available to allow communication between the pharmacist and the pharmacy technician or intern pharmacist in a manner that is sufficient to provide the personal assistance, direction, and approval required to verify and ensure delegated tasks are safely and properly performed. Technicians and intern pharmacists may not be supervised as authorized by this subsection if the required technology is not operating or available;

(B) All applicable state and federal laws are fully observed, including, but not limited to, all applicable privacy and confidentiality laws;

(C) The pharmacy technician or intern pharmacist has completed employer approved training in the activities performed and has an initial and annual documented assessment of competency. Documentation of the completed training and competency assessment must be maintained in the pharmacy’s records for a minimum of two (2) years and provided to the board or the board’s designee upon request; and

(D) The supervising pharmacist and the permit holder must maintain a sufficient audit trail of prescription/medication order data entry and modifications to a patient record performed by a pharmacy technician or intern pharmacist being supervised as authorized by this subsection. The record must include the identity of the pharmacy technician or intern pharmacist performing the data entry or modification and must be maintained in the pharmacy’s records for a minimum of five (5) years.

(3) The supervising pharmacist and permit holder shall retain responsibility for activities delegated to a pharmacy technician or intern pharmacist.

(4) Nothing in this rule shall override the provisions of 20 CSR 2220-2.010.

AUTHORITY: sections 338.010 and 338.140, *RSMo Supp. 2019*, and sections 338.013, 338.035, and 338.280, *RSMo 2016*. Original rule filed Feb. 7, 2020.

PUBLIC COST: This proposed rule will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed rule will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with the Missouri Board of Pharmacy, PO Box 625, 3605 Missouri Boulevard, Jefferson City, MO 65102, by facsimile at (573) 526-3464, or via email at pharmacy@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this rule in the *Missouri Register*. No public hearing is scheduled.

**Title 20—DEPARTMENT OF COMMERCE AND
INSURANCE
Division 2220—State Board of Pharmacy
Chapter 2—General Rules**

PROPOSED RULE

20 CSR 2220-2.725 Remote Data Entry

PURPOSE: This rule authorizes and establishes requirements for remote data entry sites.

(1) Definitions.

(A) “Remote Data Entry Sites”—A remote site located in Missouri that is operated by a Missouri licensed pharmacy and used by a pharmacy technician or intern pharmacist to electronically perform non-dispensing data entry functions, including, but not limited to, obtaining, entering, validating, or processing patient information or data.

(B) “Supervising Pharmacy”—A Missouri licensed pharmacy that is physically located in Missouri and responsible for operating a remote data entry site.

(2) Licensing.

(A) “Remote Data Entry Sites”—A permit is not required for a remote data entry site. The site shall be deemed part of and operating under the supervising pharmacy’s permit. The supervising pharmacy must maintain an address listing of all remote data entry sites in operation which must be made immediately available upon request of the board or the board’s authorized designee.

(3) Remote data entry sites must be safely operated in compliance with applicable state and federal law. The supervising pharmacy is responsible for all pharmacy operations at the remote data entry site. No medication or medical device may be located at or dispensed from a remote data entry site.

(A) Adequate security and supervision must be maintained at all times to prevent unauthorized access to the remote data entry site and equipment. Confidential records must be securely maintained to prevent unauthorized access to, and unauthorized storage/transfer of, confidential information. Any breach in the security of the remote data entry site equipment or confidential records must be documented and reported to the board in writing within seven (7) days of the breach. Paper patient or prescription records may not be generated, located, or maintained at a remote data entry site.

(B) Except as otherwise provided by state and federal requirements, the remote data entry site and the supervising pharmacy must share a common database or prescription record-keeping system that allows real-time, online access to relevant patient profile information by both the supervising pharmacy and the remote site. The identity of the pharmacy technician or intern pharmacist responsible for remotely entering, validating, or modifying data at a remote data entry site must be electronically documented/recorded in the pharmacy’s records and maintained for a minimum of five (5) years.

(C) Pharmacy technicians and intern pharmacists operating at a remote data entry site must be competent in the duties performed. At a minimum, technicians and intern pharmacists must have completed employer approved training in the activities performed remotely and must have an initial and, if applicable, annual documented assessment of competency. Documentation of the completed training and competency assessment must be maintained in the pharmacy’s records for a minimum of two (2) years and provided to the board or the board’s designee upon request;

(D) A sufficient mechanism must be in place to allow communication between the supervising pharmacist and pharmacy technician or intern pharmacist when needed. A pharmacist must be available to respond to technician/intern pharmacist questions at all times a remote data entry site is in operation and must provide the personal

assistance, direction, and approval required to verify and ensure delegated tasks are safely and properly performed. Non-dispensing data entry functions may not be performed by a pharmacy technician or intern pharmacist at a remote data entry site if the required real-time communication mechanism is not operating or available.

(E) Remote data entry sites may be inspected by the board as authorized by law. Notification by the inspector will be provided to the supervising pharmacy a minimum of seventy-two (72) hours ahead of the scheduled inspection. The supervising pharmacy permit holder must arrange for a designated representative to be present that is not a resident of the location under inspection.

(4) Policies and Procedures. The supervising pharmacy must establish written policies and procedures governing all aspects of operation of a remote data entry site that are reviewed annually by the pharmacist-in-charge. At a minimum, policies and procedures must include authorized technician and intern pharmacist activities, site security procedures and requirements, reporting security breaches, quality assurance review procedures, and staff education/training. The annual policy and procedure review date must be documented in the pharmacy’s records.

AUTHORITY: sections 338.010 and 338.140, RSMo Supp. 2019, and sections 338.013, 338.035, and 338.280, RSMo 2016. Original rule filed Feb. 7, 2020.

PUBLIC COST: This proposed rule will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed rule will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with the Missouri Board of Pharmacy, PO Box 625, 3605 Missouri Boulevard, Jefferson City, MO 65102, by facsimile at (573) 526-3464, or via email at pharmacy@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this rule in the Missouri Register. No public hearing is scheduled.

**Title 20—DEPARTMENT OF COMMERCE AND
INSURANCE
Division 2220—State Board of Pharmacy
Chapter 6—Pharmaceutical Care Standards**

PROPOSED AMENDMENT

20 CSR 2220-6.055 Non-Dispensing Activities. The board is amending sections (2), (4), and (6).

PURPOSE: This amendment establishes requirements for pharmacy technicians assisting pharmacists with non-dispensing activities authorized by the rule outside of a Missouri licensed pharmacy.

(2) Confidentiality. A pharmacist, **pharmacy technician, or intern pharmacist** performing non-dispensing activities pursuant to this rule shall comply with all applicable state and federal confidentiality laws and regulations *[and shall provide]*. *[s/Sufficient storage and security for confidential documents and electronic data processing hardware must be provided by the pharmacy permit holder or the pharmacist.* In addition, data processing systems must utilize sufficient security software to ensure confidentiality and prevent unauthorized access. Any breach in the security or confidentiality of the data processing systems or confidential documents shall be documented and reported to the board in writing within seven (7) days of the breach.

(4) A pharmacist, **pharmacy technician, or intern pharmacist** performing non-dispensing activities pursuant to this rule shall ensure compliance with Chapter 338, RSMo, and the rules of the board at all times. Nothing in this rule shall be construed to eliminate or otherwise exempt any pharmacist, **pharmacy technician, intern pharmacist, or pharmacy permit holder** from the record-keeping, confidentiality, or security requirements otherwise imposed by Chapter 338, RSMo, or the rules of the board. Violations of this section shall constitute grounds for discipline.

[(6) A pharmacy permit shall be required for performing non-dispensing activities if the pharmacist is using a pharmacy technician to assist in the practice of pharmacy at the location where non-dispensing activities are being performed, provided that a pharmacy permit shall not be required for sites used solely by the pharmacist for administering vaccines as authorized by Chapter 338, RSMo, and the rules of the board. Pharmacy technicians shall only be authorized to work under the direct supervision of a pharmacist as provided by section 338.013, RSMo, and 20 CSR 2220-2.700.]

(6) A pharmacy technician and intern pharmacist may be used to assist a pharmacist with non-dispensing activities outside of a pharmacy subject to the following:

(A) The pharmacy technician/intern pharmacist must be under the direct supervision of a Missouri licensed pharmacist as required by 20 CSR 2220-2.710. The supervising pharmacist must ensure pharmacy technician/intern pharmacist activities comply with state and federal law and must provide the personal assistance, direction, and approval required to verify and ensure delegated non-dispensing activities are safely and properly performed;

(B) The pharmacy technician or intern pharmacist must have completed employer approved training in the activities performed and have an initial and, if applicable, annual documented assessment of proficiency. Documentation of the completed training and proficiency assessment must be maintained in the pharmacy's records for a minimum of two (2) years and provided to the board or the board's designee upon request;

(C) A sufficient mechanism must be in place to allow real-time communication between a pharmacist and the technician/intern pharmacist when needed. A pharmacist must be available to respond to pharmacy technician/intern pharmacist questions at all times non-dispensing activities are being performed; and

(D) Adequate security and supervision must be maintained at all times to prevent unauthorized access to, and unauthorized storage/transfer of, confidential patient information or patient records.

(E) The provisions of this section (6) do not apply to technicians or intern pharmacists engaged in delivering filled prescriptions/medication orders on behalf of the pharmacy as authorized by 20 CSR 2220-2.013.

AUTHORITY: sections 338.010 and [338.220] 338.140, RSMo Supp. [2009] 2019, and sections [338.140] 338.035 and 338.220, RSMo [2000] 2016. Emergency rule filed Oct. 23, 2009, effective Nov. 2, 2009, expired April 30, 2010. Original rule filed Oct. 22, 2009, effective June 30, 2010. Amended: Filed Feb. 7, 2020.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the

Missouri Board of Pharmacy, PO Box 625, 3605 Missouri Boulevard, Jefferson City, MO 65102, by facsimile at (573) 526-3464, or via email at pharmacy@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this rule in the Missouri Register. No public hearing is scheduled.